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| 10/719,298 | 11/21/2003 | Navroz Boghani | 261088US0 | 2138 |

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| EXAMINER |
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GEORGE, KONATA M

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| ART UNIT | PAPER NUMBER |
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1616

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03/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/719,298 | Applicant(s) BOGHANI ET AL. | |
| | Examiner KONATA M. GEORGE | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37, 47, 64-70 and 88-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37, 47, 64-70 and 88-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/27/07; 1/17/08; 2/6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-37, 47, 64-70 and 88-92 are pending in this application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 27, 2007; January 17, 2008 and February 6, 2008 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Action Summary

The examiner acknowledges the cancellation of claims 38-46, 48-63 and 71-87. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.

The rejection of 1-37, 47, 64-70 and 88-91 under statutory type (35 U.S.C. 101) double patenting rejection over claims 1-37, 47, 63-70 and 88-91 of copending application 11/083,968 is hereby withdrawn in view of applicant amendment to the claims.

The provisional rejection of claims 1, 2, 8-10, 21 and 22 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1, 4, 5 and 8-12 of copending application 11/134,356 is being maintained for the reasons stated in the office action dated June 18, 2007.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 8-10, 21 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5 and 8-12 of copending Application No. 11/134,356. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is directed to a delivery system comprising an active component encapsulated within an encapsulating material and the copending application is a composition comprising the delivery system of the instant invention. Encapsulated delivery systems are well known in the cosmetic art for use in deodorants, foundations, etc. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use an encapsulated active agent as instantly claimed in a cosmetic composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant request that this rejection be held in abeyance. The examiner cannot grant this request and the rejection is maintained.

The provisional rejection of claims 1, 2, 5-11, 21 and 22 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6 and 11-21 of copending application 11/134,365 is being maintained for the reasons stated in the office action dated June 18, 2007.

Claims 1, 2, 5-11, 21 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6 and 11-21 of copending Application No. 11/134,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed towards a delivery system comprising an active agent and an encapsulating material. The difference is that in application '365 the delivery system has a water-retention value of up to 5%, whereas the instant invention is silent with respect to water-retention value. It is the position of the examiner that since both delivery systems comprise the same active agent, encapsulating material and tensile strength, the water-retention value would also be the same and would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant request that this rejection be held in abeyance. The examiner cannot grant this request and the rejection is maintained..

The provisional rejection of claims 1-11, 21 and 22 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 11-19 and 21-23 of copending Application No. 11/134,367 is being maintained for the reasons stated in the office action dated June 18, 2007.

Claims 1-11, 21 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 11-19 and 21-23 of copending Application No. 11/134,367. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a delivery system comprising an active agent and an encapsulating material. The difference is that in application '367 the delivery system comprises two or more active agents. The instant invention recites that the delivery system can contain "at least one" active component. This recitation does not limit the delivery system to containing just one active component, but allows for several active components to be added if necessary and is thus obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant request that this rejection be held in abeyance. The examiner cannot grant this request and the rejection is maintained.

The provisional rejection of claims 1 and 8-10 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7-9 of copending Application No. 11/134,370 is being maintained for the reasons stated in the office action dated June 18, 2007.

Claims 1 and 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7-9 of copending Application No. 11/134,370. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is directed to a delivery system comprising an active component encapsulated within an encapsulating material and the copending application is a delivery system comprising an encapsulated active component onto which an additional coating material is applied. The application of additional coatings onto particles is well known in the art for several reasons, 1) to stabilize particles, 2) for sustained or rapid release drug delivery, 3) selective target delivery of a drug. Therefore, adding an additional coating to the drug delivery system would have been obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant request that this rejection be held in abeyance. The examiner cannot grant this request and the rejection is maintained.

The provisional rejection of claims 1, 2, 5, 8-10 and 21 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 11-14 and 16 of copending Application No. 11/134,371 is being maintained for the reasons stated in the office action dated June 18, 2007.

Claims 1, 2, 5, 8-10 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 11-14 and 16 of copending Application No. 11/134,371. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a delivery system comprising an active agent and an encapsulating material. The difference is that in application '371, the delivery system has an active component and encapsulating material contained in a ratio of from 1:99 to 70:30, whereas the instant invention is silent with respect to water-retention value. It is the position of the examiner that since both delivery systems comprise the same active agent, encapsulating material, and tensile strength, the ratio would also be the same and would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant request that this rejection be held in abeyance. The examiner cannot grant this request and the rejection is maintain.

The provisional rejection of claims 1-10, 21 and 22 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9 and 12-21 of copending Application No. 11/134,480 is being maintained for the reasons stated in the office action dated June 18, 2007.

Claims 1-10, 21 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9 and 12-21 of copending Application No. 11/134,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a delivery system comprising an active agent and an encapsulating material. The difference is that in application '480, the particles have a particles size of from about 125 to about 900 microns. Claims 19-20 of the instant invention claims particle sizes which falls within the scope of particle size as claimed in the copending application and is considered obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant request that this rejection be held in abeyance. The examiner cannot grant this request and the rejection is maintained.

The provisional rejection of claims 1, 2, 5, 8, 9 and 11 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-10, 12, 18 and 30-39 of copending Application No. 11/135,153 is being maintained for the reasons stated in the office action dated June 18, 2007.

Claims 1, 2, 5, 8, 9 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-10, 12, 18 and 30-39 of copending Application No. 11/135,153. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a delivery system comprising an active agent and an encapsulating material and having a tensile strength of at least 6,500 psi. The difference is that in application '153, the delivery system has a water absorption of about 0.01 to about 50%, whereas the instant invention is silent with respect to water absorption. It is the position of the examiner that since both delivery systems comprise the same active agent, encapsulating material, and tensile strength, the water absorption rate would also be the same and would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant request that this rejection be held in abeyance. The examiner cannot grant this request and the rejection is maintain.

The rejection claims 1-5, 8, 18, 21, 22, 47 and 64-66 under 35 U.S.C. 102(b) as being anticipated by Kitajima et al. is being maintained for the reasons stated in the office action dated June 18, 2007.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 8, 18, 21, 22, 47 and 63-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitajima et al. (US 3,691,090).

Kitajima et al. teach a process for the preparation of capsules containing a core material and an encapsulating material (col. 1, lines 39-41). Column 2, lines 8-15 teaches that the core material selected from foods, enzymes, medicines, etc. Column 2, lines 20-26 teach examples of the encapsulating material of which ethylcellulose, and polyvinyl acetate are mentioned. Example 3 teaches a method of making aspirin containing capsules, wherein ethylcellulose is the encapsulating material. Kitajima et al. is silent with respect to the tensile strength of the particle. Tensile strength of the particle depends on the encapsulating material used. Since Kitajima et al. teach the

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claimed encapsulating material the limitation of tensile strength of the particle will be inherent.

Response to Arguments

Applicant's arguments filed on December 17, 2007 have been fully considered but they are not persuasive.

Applicant argues that the capsules will not, each and every time, have the minimum tensile strength as claimed. It is the position of the examiner that the prior art reference of Kitajima et al. teach the claimed invention. As stated above, the prior art teaches the same claimed active agent and the same claimed encapsulating material therefore, since the composition is the same, the tensile strength would be inherent. It is unclear to the examiner, how, if the composition of the prior art is the same as the claimed invention, the tensile strength is not inherent.

The rejection of claims 1, 2, 5, 12, 13 and 18-20 under 35 U.S.C. 102(b) as being anticipated by Leinen is hereby withdrawn in view of applicant arguments.

The rejection of claims 1-16, 18-25, 27-32, 34-37, 47, 64-70 and 89-91 under 35 U.S.C. 102(b) as being anticipated by Schobel et al. is being maintained for the reasons stated in the office action dated June 18, 2007.

Claims 1-16, 18-25, 27-32, 34-37, 47, 63-70 and 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Schobel et al. (US 4,824,681).

Schobel et al. disclose an encapsulated sweetener (abstract). Column 5, line 55 through column 6, line 10 teach the sweetening agents which can be used in the invention. Column 6, lines 25-28 teach the particles size from about 150 to 300 microns. Column 7, lines 12-41 teaches that the coating material comprises a hydrophobic polymer and a hydrophobic plasticizer, wherein the polymer can be polyvinyl acetate phthalate and the polymer is about 55% to about 95% of the coating material. Example 1 teaches a method of making encapsulated high intensity sweetener aspartame, wherein the particles contain from 94.3% to 96.2% of the sweetener. Examples 3-6 teach a chewing gum comprising from about 1.7 to 2.7% of the encapsulated material together with additional flavoring agents. Schobel et al. is silent with respect to the tensile strength of the particle. Tensile strength of the particle depends on the encapsulating material used. Since Schobel et al. teach the claimed encapsulating material, the limitation of tensile strength of the particle will be inherent.

Response to Arguments

Applicant's arguments filed on December 17, 2007 have been fully considered but they are not persuasive.

Applicant argues that the capsules will not, each and every time, have the minimum tensile strength as claimed. It is the position of the examiner that the prior art reference of Schobel et al. teach the claimed invention. As stated above the prior art

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teaches the same claimed active agent and the same claimed encapsulating material therefore, since the composition is the same, the tensile strength would be inherent. It is unclear to the examiner, how, if the composition of the prior art is the same as the claimed invention, the tensile strength is not inherent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37, 47, 64-70 and 88-92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37, 47, 63-70 and 88-91 of copending Application No. 11/083,968. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications claim a delivery system comprising a least one

active component encapsulated within an encapsulating material. The difference between the two is the minimal tensile strength of the system. In the instant invention the tensile strength is at least 10,000 psi and the copending application has a tensile strength of at least 6,500 psi. Because the copending broadly discloses the same range as the instant invention it is obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-37, 47, 64-70 and 88-92 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Art Unit 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616